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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,044	05/04/2001	Dusan Pavcnik	PA-5252-RFB	9073

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EXAMINER	
STEWART, ALVIN J	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
03/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/849,044	PAVCNIK ET AL.	
	Examiner	Art Unit	
	Alvin J. Stewart	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/26/07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-9 and 12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 12/26/07 have been fully considered but they are not persuasive.

After a careful examination of the previous office action and the Applicant's point of view the Examiner still believes that the rejection is still proper.

The Applicant's representative argues that the prior art does not disclose a proximal end of the stent that is located upstream of the distal end of the stent and the distal end of the stent providing a distal outflow end of the stent graft through which blood exits.

The Examiner completely disagrees with the Applicant's representative point of view. For example, the stent-graft is clearly placeable at a vascular treatment site (the prior art clearly shows that functional limitation).

Regarding the proximal end of at least one stent that is located upstream of the distal end of the stent and the distal end of the stent providing a distal outflow end of the stent graft through which blood exits, the see below to see the interpretation of the Examiner's point of view:

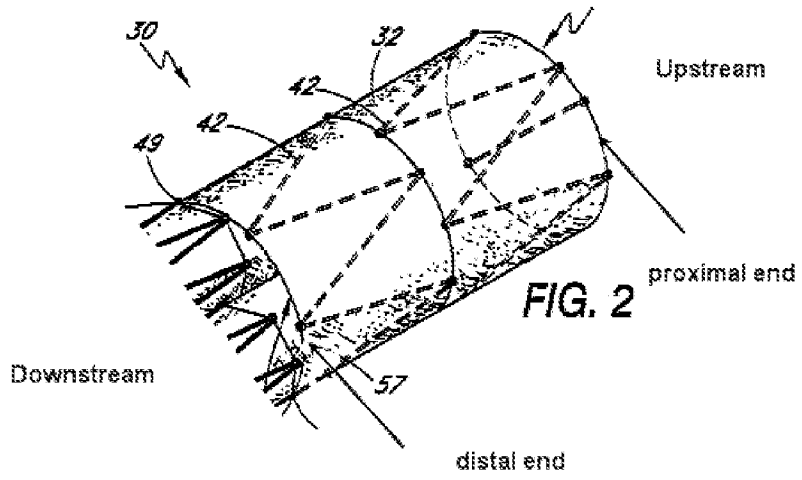

FIG. 2

The use of the broad limitation "at least one stent" has been interpreted broadly and the examiner used the two stents 42 at the right side of Figure 2 as the limitation "at least one stent". Therefore, the two portions of the layer are along an outside surface and inside surface of the stent and the layer is secured to at least the distal end of one stent as shown in the figure above.

The new limitations claimed by the Applicant's representative clearly show a proximal end of the stent located at an upstream and a distal end of the stent located at a downstream, with respect to the Examiner's stents (42), no matter stents 42 are attached to stents 48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-7, 12-16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas US Patent 6,090,128 in view of Gregory US Patent 5,990,379.

Douglas discloses an implant comprising a plurality of stents (42) covered by a sleeve (32, 34 & 36). The stents have proximal and a distal ends. The sleeve has a length ***about*** equal to twice the length of the stent (the Examiner is referring to the two stent 42 shown in Figure 2, that are folded with the sleeve 32 because the Applicant's representative is referring to at least one stent). The sleeve has a first portion within the inside surface of the stent and a second portion that is folded back over the proximal end of the stent (see element structure 38 in Fig. 2). The second portion extends from the proximal end to the distal end, along an outside surface of

the stent (see Fig. 2). Also, the first portion and the second portion are secured to at least the distal end of the stent (see Fig. 2, elements 40, 57, 59 61).

Additionally, the first portion and the second portion of the sleeve are secured to at least the distal end of the at least one stent. See Figure 2 and col. 9, lines 10-20 disclosing the second end of the at least one stent secured by stitches.

Finally, Douglas discloses stents having a frame comprising eyelets at the proximal and distal ends wherein the stents are connected to each other by biocompatible filaments. However, Douglas does not disclose a covering of collagen having an extracellular matrix layer.

Gregory teaches an implant comprising a stent (20) and a graft (16) made of extracellular matrix. The stent has a proximal end and a distal end. The sleeve has a length ***about*** equal to twice the length of the stent (see Figs. 8-10). The sleeve has a first portion within the inside surface of the stent and a second portion that is folded back over the proximal and distal end of the stent. The second portion extends from the proximal end to the distal end, along an outside surface of the stent (see Figs. 8-10 and col. 14, lines 10-20 and lines 31-36) for the purpose of inhibiting the migration of smooth muscle cells in the treated area (see col. 1, lines 22-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material property of the Douglas reference with the extracellular matrix of the Gregory reference in order to inhibit the migration of smooth muscle cells in the treated area.

Regarding claim 19, see Figures 1 and 7A-7G.

Claims 8, 9, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas US Patent 6,090,128 in view of Gregory US Patent 5,990,379 and further in view of Buirge et al US Patent 5,693,085.

Douglas in view of Gregory discloses the invention substantially as claimed. However, Douglas in view of Gregory does not specifically disclose a graft made of SIS material.

Buirge et al teaches an stent having a graft made of SIS (see col. 7, lines 42-67; col. 9, lines 64-67 and col. 10, lines 1-9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Douglas reference with the SIS material of the Buirge reference in order to inhibit the migration of smooth muscle cells in the treated area.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

March 22, 2008.